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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/746,712	12/21/2000	Joseph Andrew Chinn	CMI-397	3630
23720	7590	04/25/2005	EXAMINER	
WILLIAMS, MORGAN & AMERSON, P.C. 10333 RICHMOND, SUITE 1100 HOUSTON, TX 77042			SWEET, THOMAS	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 04/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/746,712

Applicant(s)

CHINN ET AL.

Examiner

Thomas J Sweet

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 9-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5 and 6 is/are rejected.
- 7) ☒ Claim(s) 3,4,7 and 8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/19/03
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group I including only claims 1-8 in the reply filed on 04/05/2005 is acknowledged.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2 and 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Darouiche et al. (US 5,624,704) in view of Holley et al. (US 6,585,767). Darouiche et al. discloses a method of treating an implantable device (title) such as a heart valve (col 4, line 44) by providing an antibiotic solution comprising minocycline and rifampin (col 3, lines 13-17) dissolved in a solvent (cols 3-4, lines 55-16), contacting (abstract) said material suitable (implant) for retaining an antibiotic and said antibiotic solution to obtain an antimicrobial reservoir, removing the solvent from said antimicrobial reservoir (abstract, drying). However, Darouiche et al. does not disclose the implantable heart valve being of the construction of a valve orifice defining a blood flow area, a leaflet coupled to said orifice for movement between an open position and a closed position, and a sewing cuff coupled to said orifice, said sewing cuff comprising a material suitable for retaining an antibiotic and implanting said heart valve to provide resistances to pannus overgrowth. Holley et al. Teaches another heart valve comprising a

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valve orifice defining a blood flow area (col 1, line 5), a leaflet coupled to said orifice for movement between an open position and a closed position (col 1, lines 6-9) , and a sewing cuff coupled to said orifice (col 1, lines 27-28), said sewing cuff comprising a material suitable for retaining an antibiotic (col 1, lines 27-28) contacting said material suitable for retaining an antibiotic (fig. 3) to obtain an antimicrobial reservoir on the cuff for the purpose of preventing infection after the step of implanting said heart valve. It would have been obvious to one of ordinary skill in the art at the time the invention was made to alternatively treat a heart valve sewing cuff as taught by Holley et al. using the method of Darouiche et al. in order to prevent infection after the step of implanting a heart valve. Such a modification amounts to mere substitution of one antimicrobial reservoir for another in the art of heart valves and would inherently provide resistances to pannus overgrowth since the structure is the same as the present claimed invention.

With regard to claims 2 and 6, solvent can be methanol (Col 6, lines 13-18).

With regard to claim 6, Holley et al. teaches said sewing cuff being coupled to said exterior peripheral surface of said heart valve (col 1, lines 40-44).

Claims 1-2 and 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shu et al. (US 5,948,019) in view of Darouiche et al. (US 5,624,704). Shu et al. discloses a method of providing resistance to pannus overgrowth to an implantable prosthetic heart valve (title) comprising; providing an implantable heart valve (such as prior art fig. 1) comprising a valve orifice (12) defining a blood flow area, a leaflet (12.1) coupled to said orifice for movement between an open position and a closed position (col 1, lines 13-24), and a sewing cuff (14)

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coupled to said orifice, said sewing cuff comprising a material suitable for retaining an antibiotic (semi-permeable) and implanting said heart valve (col 1, lines 25-42). However, Shu et al. does not disclose providing an antibiotic solution comprising minocycline and rifampin dissolved in a solvent contacting said material suitable for retaining an antibiotic and said antibiotic solution to obtain an antimicrobial reservoir and removing the solvent from said antimicrobial reservoir. Darouiche et al. teaches another heart valve (col 4, line 44) treated by a method providing an antibiotic solution comprising minocycline and rifampin (col 3, lines 13-17) dissolved in a solvent (cols 3-4, lines 55-16), contacting (abstract) said material suitable (implant) for retaining an antibiotic and said antibiotic solution to obtain an antimicrobial reservoir, removing the solvent from said antimicrobial reservoir (abstract, drying) for the purpose of preventing infection after implantation. It would have been obvious to one of ordinary skill in the art at the time the invention was made to treat a heart valve including the sewing cuff as taught by Shu et al using the method of Darouiche et al. in order to prevent infection after the step of implanting a heart valve.

With regard to claims 2 and 6, solvent can be methanol (Col 6, lines 13-18).

With regard to claim 6, the sewing cuff of Shu et al is coupled to said exterior peripheral surface of said heart valve, so inherently at some point a step on coupling was preformed.

#### ***Allowable Subject Matter***

Claims 3-4 and 7-8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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The following is an examiner's statement of reasons for allowance: The prior art of record does not teach or render obvious using supercritical carbon dioxide as a solvent for the combination of minocycline and rifampin used for coating a heart valve sewing cuff.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee.

Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J Sweet whose telephone number is 571-272-4761. The examiner can normally be reached on 6:30 am - 5:00pm, M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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